



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1999-D-0178]

Guidance for Industry on Interpreting Sameness of Monoclonal Antibody Products under the Orphan Drug Regulations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations." The purpose of this guidance is to provide sponsors and manufacturers FDA's current thinking on the criteria by which two monoclonal antibody products would be considered the same under the Orphan Drug Act and implementing regulations.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marjorie Shapiro, Center for Drug Evaluation and Research (HFD-123), Food and Drug Administration, 9000 Rockville Pike, Bethesda, MD 20892, 301-827-0710, or Henry Startzman, Office of Orphan Products Development, Office of Special Medical Programs, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20993, 301-796-8660.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations."

On July 26, 1999 (64 FR 40381), FDA announced the availability of the draft version of this guidance. The public comment period closed on October 25, 1999. A number of comments were received from the public, all of which the Agency considered carefully as it finalized the guidance and made appropriate changes. Any changes to the guidance were minor and made to clarify statements in the draft guidance.

In the Federal Register of December 29, 1992 (57 FR 62076), FDA published the orphan drug regulations final rule, and on June 12, 2013 (78 FR 35117) the Agency finalized certain amendments to the final rule in order to clarify regulatory provisions and make minor improvements to address issues that have arisen since 1992. The final rule established in part 316 (21 CFR part 316) regulations that prescribe certain incentives for the development of "orphan drugs", drugs which are intended for use in rare diseases or conditions. One of the incentives for orphan drug development is to obtain exclusive approval for the pioneer product for a period of 7 years during which no approval will be given to a subsequent sponsor of the same drug product for the same indication unless it proves to be clinically superior, as defined in

§ 316.3(b)(3). In determining whether or not two products would be considered the same, FDA recognized that different criteria were necessary for macromolecules versus small molecules (§ 316.3(b)(13)).

Macromolecules include a variety of structures including proteins, nucleic acids, carbohydrates and closely related, complex, partly definable drugs such as live viral vaccines. The current definition of sameness for protein drugs (§ 316.3(b)(13)(ii)(A)), however, does not consider the unique nature of antibodies. This final document is intended to describe FDA's thinking on the criteria by which two monoclonal antibody products would be considered the same under the Orphan Drug Act and its implementing regulations.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## III. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) and have been approved under OMB control numbers 0910-0167 (21 CFR part 316), 0910-0001 (21 CFR part 314), and 0910-0014 (21 CFR part 312).

#### IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: April 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.